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EDITOR'S PAGE

Innovation

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Innovation is the driving force that produces advances in medicine in general, and cardiology in particular. I have just returned from the British Cardiac Society meeting where I served as chair of a fascinating session on medical innovation. The speakers included Mandy Haberman, a woman who invented the nonspill baby cup, and Andrew Cleeland, who administered the development of renal artery denervation for hypertension. I was especially lucky to hear a magnificent presentation by Dr. Alain Cribier who, as the Paul Wood lecturer, discussed the process of innovation in the context of his development of transcatheter aortic valve replacement (TAVR or TAVI, take your pick). In aggregate these lectures highlighted the challenges and requirements inherent to bringing a novel idea from conception to a finished product with clinical application of value to society.

All speakers stressed the fact that successful innovation had to begin with the identification of an unmet need. This concept seems pretty obvious, since all of us are regularly confronted by problems that lack solutions. However, at least for me, the tendency has just been to accept that there is no solution for some conditions, and attempt to deal with the dilemma as best as possible. Very often innovation is the results of a chance observation. In fact, the one procedure that I had a role in discovering with Bill Bommer, that is myocardial contrast echo, was the result of wondering what would happen if microbubbles were injected into the coronary arteries. It was only after seeing the myocardium opacify that we recognized that this might be a useful technique to assess myocardial perfusion and coronary blood flow. So, simple as it sounds, there is a definite skill in identifying an unmet need and conceptualizing an answer. Fortunately for us, serendipity often compensates for the lack of forethought.

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Once an unmet need is recognized and a plausible solution is identified, a successful innovator has to be a risk taker and be willing to fail. This may be the most difficult aspect of the process for most of us. Physicians have generally been extremely successful in life, and the concept of risking almost everything on an unproven idea with a significant likelihood of failure is not readily accepted. In fact, it is often said that one of the major limitations of funding agencies, such as the National Heart, Lung, and Blood Institute, is that they seek assurances that proposed projects will be successful before support is provided. Consideration of clinically important procedures done on a daily basis that were developed without significant National Institutes of Health support, such as echocardiography, coronary bypass surgery, angioplasty/stents, and pharmaceuticals, such as beta-blockers, lends credence to this concept. The potential for failure is inherent in innovation, and can provide a significant barrier to success.

Dr. Cribier and the other speakers also emphasized the need for true innovators to be passionate and driven to achieve their goal. Novel ideas rarely lead to straightforward implementation. Rather, there are usually obstacles along the way, each of which must be overcome. The innovator must be relentless in pursuit of the solution. This is especially true in regard to the skepticism that is typically encountered early in the process. All of the speakers indicated that they were told in the initial stages that their ideas would never work, or if they could be implemented would have been done such a long time ago. So overcoming

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obstacles in the face of skepticism that the new idea could be successful requires a unique personality, and one that characterizes the true innovator.

Having identified an unmet need and conceived a solution, the innovator has to obtain the necessary financial and other support to carry out the development. This requires convincing individuals who have resources to devote them to a project with an inherent risk of failure, which is not an easy task. Each of the speakers related the number of times they were turned down for support before a willing source was identified. Additional steps also involve obtaining patents and other legal issues. Medical education almost never provides physicians with the knowledge of how this is done or the skill set to do it successfully. Some institutions, such as UCSD and Emory, have begun to develop translational research training programs that include financial and regulatory aspects of innovation in addition to the scientific aspect. Whether and when in the training process this should be done, if at all, received varying opinions from the speakers. Nevertheless, it is clear that innovation requires not only discovery, but also marketing.

Once the innovation is shown to be feasible, the process now turns to how to deal with enhancements and competition. While skepticism abounds in the early stages, after a novel idea has been shown to be possible individuals often come forth with proposed improvements or even competing inventions. While incorporation of improvements is clearly part of the innovative process, mere copies of the new discovery can potentially deny credit and reward to the innovator and also blunt the incentive for future breakthroughs. Given the financial, legal, and regulatory issues that must be dealt with in implementing a novel idea, and the lack of education of physicians in these matters, it is often critically important to assemble a team that can properly bring the innovation to the clinical setting.

A number of other issues arose during this interesting session. The role of the inventor in the testing of the innovation regarding conflict of interest was questioned, as was the importance of financial reward. The requirement for inventors to be uninvolved in the clinical testing of their ideas seems to be especially stringent in medicine. Dr. Cribier, for his part, told me that his major interest was in seeing the TAVR procedure developed and implemented, and that he relinquished financial rights early in the process. However, Andrew Cleeland extolled the fact that the successful sale of renal denervation had appropriately rewarded not only the innovators, but also many other individuals who took the risk of casting their future with an unproven technology and contributed significantly to its ultimate success. There are obviously a number of ways to view these issues.

The process of innovation is at once daunting and exhilarating. Serendipity often leads to critically important advances in medicine, witness penicillin. However, it is the recognition of an unmet need accompanied by the vision of a possible solution, that is then developed to the point of clinical application, that captures our imagination and respect. I believe that innovation requires a special mindset and character, one that is visionary, passionate, relentless, risk taking, and willing to fail. Dr. Cribier told me that he held multiple patents (I believe that he said nine), but that along the way he had also experienced failure with a several of his novel ideas. The entire innovative process will frequently require a team of individuals with similar characteristics. I think that greater training in translational skills would enable physicians to participate more fully in the innovative process, but that discoveries will likely continue to emanate from a small group of unique individuals. When the history of medicine is written, it will almost certainly be the activities and achievements of these true innovators that will be most often recounted.

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